

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Application No.: 10/643,673
Filing Date: August 19, 2003
Applicant: Suong-Hyu Hyon, et al.
Group Art Unit: 1796
Examiner: Susan W. Berman
Title: ULTRA HIGH MOLECULAR WEIGHT POLYETHYLENE MOLDED
ARTICLE FOR ARTIFICIAL JOINTS AND METHOD OF PREPARING
THE SAME
Attorney Docket: 1736-000001/REC

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REPLY BRIEF UNDER 37 CFR § 41.41

This Reply Brief is filed in response to the Examiner's Answer mailed December 18, 2009 (herein, the "Answer"), in the appeal from the Office Action mailed December 22, 2008 (herein the "Final Action") and the subsequent Advisory Action mailed May 22, 2009, for which a Notice of Appeal was filed on April 22, 2009.

Arguments

I. The claims do not recapture surrendered subject matter.

All claims have been rejected under 35 U.S.C. § 251, as allegedly being an improper recapture of subject matter surrendered in the application for the patent (U.S. Patent No. 6,168,626, Hyon et al., issued January 2, 2001, herein referred to as “the ‘626 Patent”) upon which the present reissue is based. As Applicants discussed in their Brief, the recapture rejection should be reversed, for either or both of two reasons.

- First, the present reissue claims were prosecuted for a different invention than that prosecuted in the ‘626 Patent, so that broadening aspects do not relate to surrendered subject matter.
- Second, even if the present claims are viewed as having broadening aspects related to surrendered subject matter, they are materially narrowed in other aspects so as to avoid recapture.

Thus, rejection fails under either or both of the second and third prongs of the analysis outlined in *Pannu v. Storz Instruments, Inc.*, 258 F.3d 1366, 59 U.S.P.Q.2d 1597 (Fed. Cir. 2001).

Applicants submit that there is little disagreement as to many of the facts underlying the Examiner’s and Applicants’ analyses of the recapture rejection. Rather, the analyses differ regarding the legal significance of those facts, in particular regarding the significance of the narrowing aspects of the appealed claims relative to those presented, prosecuted, and issued in the ‘626 Patent.

As recited in the Answer – and as Applicants acknowledged in their Brief – the currently appealed reissue claims contain claim elements that are broader in some regards than aspects of the claims in the ‘626 Patent. The current claims also contain limitations not present in the originally

filed reissue claims from which they are derived. The history of amendment during prosecution of the appealed claims does not change the fact that, as originally filed, the reissue claims were deemed independent and distinct from the claims of the '626 Patent. The steps of compression deforming and cooling cited by the Examiner in the Answer (page 9) were added to the appealed claims to overcome art (U.S. Patent 5,414,049) that was not applied in the prosecution of the '626 Patent. This underscores the material differences between the present reissue claims, as filed, from the claims of the '626 Patent. Thus, whatever their current form, the present claims do not represent an attempt to re-prosecute the original claims of the '626 Patent.

The recapture rule is grounded in principles of equity, as is the law of reissues in general. See, *Ball Corp. v. United States*, 729 F.2d 1429, 1435, 221 U.S.P.Q. 289, 296 (Fed. Cir. 1984), *In re Clement*, 131 F.3d 1464, 45 U.S.P.Q.2d 1161, 1165 (Fed. Cir. 1997). A finding of recapture is thus factually dependent and, Applicants submit, not susceptible to "bright line" rules which either allow or preclude broadening of reissue claims relative to claims prosecuted in the patent to be reissued. Applicants respectfully submit that the analysis underlying the present recapture rejection has been focused predominantly on those aspects of the appealed claims that are broader than allegedly corresponding aspects of the claims of the '626 Patent, with little consideration of the countervailing narrowing imparted by the below the melting point temperature limitation of the claims. As is clear from the law, the recapture analysis cannot end with a simple conclusion that a reissue claim presents broadened aspects. Material narrowing of reissue claims can obviate such a rejection. The Answer now attempts to address the below the melting temperature limitation of the appealed claims. But, Applicants respectfully submit, the analysis is conclusory, and inconsistent with both the technical significance of the below the melting point limitation and the admitted relevance of the limitation to distinguishing the art.

In particular, in an attempt to diminish the significance of the present claims as having been directed to a patentably distinct invention, the Examiner suggests that the narrowing limitation of heating below the melting point does not “present an issue unrelated to the original patented claims and the prosecution thereof” because the recited temperature limitation is “included in the recitation ‘heating the crosslinked ultra high molecular weight polyethylene molded block up to a compression deformation temperature’ and ‘compression-deforming the block’ in claim 3 of US ‘626.” Answer, at page 9. The fact that the narrowing limitation of the appealed claims falls within a broadly stated heating requirement of the ‘626 Patent claims does not, however, diminish the limitation’s technical and legal significance. Indeed, the Answer acknowledges that this limitation does narrow the claims (Answer, at page 9) and that this limitation distinguishes the art that was the subject of the original prosecution of the ‘626 Patent (Answer, at page 12). Thus, the limitation does have significance in defining a patentable invention.

Further, the analysis in the Answer attempts to address the facts in the court cases discussed in Applicant’s Brief. In recognition of the factual focus of the recapture analysis (as noted above) Applicants compared and contrasted the facts underlying the present appeal from the facts described in several of the leading court decisions regarding recapture, so as to illustrate situations in which recapture was, and was not, found. The Examiner now addresses two of those cases: *Mentor Corp. v. Coloplast, Inc.*, 998 F.2d 992, 996, 27 U.S.P.Q.2d 1521, 1525 (Fed. Circ. 1993), and *Pannu v. Storz Instruments, Inc.*, *supra*. The Examiner equates the below the melting point limitation of the appealed claims to the “flexible” claim element that the *Mentor* court found not sufficiently limiting relative to the “resilient” term recited in the originally issued patent. Likewise, the Examiner equates the present narrowing limitation to the “three time greater” claim term discussed in *Pannu*, relative to the “substantially greater” claim term in the originally issued patent. The Examiner then

alleges, “The recitation ‘heating ... to compression deformable temperature between 50 °C below the melting point of said article and said melting point’ in the instant claims is not considered to materially limit the scope of a claim that recites heating wherein the ‘compression deformable temperature is in a range of to 50 °C lower than ... the melting temperature of the crosslinked ultra high molecular weight polyethylene to 80 °C higher than the melting temperature’ in claim 5 of US ‘626.” Answer, at page 11.

Applicants submit that this conclusory statement is both technically and legally incorrect. Technically, the below the melting point limitation dramatically reduces the scope of temperatures at which the claimed process operates. This is evident even if one compares the narrowed range to the range of Claim 5 of the ‘626 Patent recited in the Answer. This narrowing is even more marked relative to the broadest method claim of the ‘626 Patent, method Claim 3, which merely requires heating to a compression deformable temperature. (The Answer provides no rationale for why comparison is made only to Claim 5, rather than to Claim 3.) Even when viewed simply from a quantitative perspective, the appealed claims subsume only about 38% of the temperature range of Claim 5 of the ‘626 Patent. Relative to the much broader range of temperatures subsumed by Claim 3, the appealed claims are even more significantly narrowed. Further, from a qualitative perspective, it is manifest that a process which requires deformation of a material is highly temperature dependent – heating the material above its melting point is, indeed, materially different than melting below its melting point.

Moreover, contrary to the Examiner’s analysis, the below the melting point narrowing limitation is legally significant. As noted above, the Examiner has acknowledged that this limitation would have been sufficient to distinguish the art applied during original prosecution of the ‘626 Patent. See, Answer at page 12, and the discussion at pages 25-26 of the Brief. This limitation also

operated during prosecution of the appealed claims to overcome a rejection under 35 U.S.C. 102(b) based on U.S. Patent No. 3,886,056, *Kitamaru et al.*, issued May 27, 1975 (herein "*Kitamaru*"). In the Final Action, the Examiner stated,

The rejection of claim 104, 109, 114, 149-152 and 154-157 as being anticipated by *Kitamaru et al* (3,886,056) is withdrawn. *Kitamaru et al* teach extending UHMWPE under pressure in the molten state, while the instantly claimed method is now limited to temperatures between 50°C lower than the melting point and the melting point of the UHMWPE.

Final Action, at page 5 (emphasis added). Contrary to the conclusory statement made in the Answer, the below the melting point limitation -- by the Examiner's own analysis -- materially limits the scope of the claim, as it was the very reason that the present claims were found to overcome the §102 rejection based on *Kitamaru*.

As discussed in the Brief, the material significance of the below the melting point limitation in the appealed claims is also evidenced by the fact that is not completely unrelated to a rejection made during prosecution of the original patent. See, *In re Clement*, 45 U.S.P.Q.2d 1161 (Fed. Circ. 1997). In an attempt to refute this point, however, the Examiner states, "Appellant has not pointed to a rejection wherein the compression-deformation temperature was an issue" and "... the compression-deformation temperature was not an issue in the rejection set forth in the prosecution of the '626 Patent." Answer at page 12. Applicant submits that the Examiner's analysis misapprehends *In re Clement*, and imposes requirements not supported by the case law regarding the timing of when the limitation must have been presented, the scope of the analysis relative to the rejection, or both.

First of all, the Examiner's analysis appears to require that the below the melting temperature limitation must actually have been at issue during original prosecution. *In re Clement* makes no such requirement. (Indeed, if the limitation had been actually presented, it could not be a

new limitation added during reissue.) Rather, *In re Clement* analysis is retrospective. It only requires that the limitation be germane to a rejection, i.e, it would have had significance in the analysis of a rejection made during original prosecution had it been presented.

Further, the apparent focus of the Examiner's analysis on the specific limitation itself is neither supported by *In re Clement*, nor consistent with the "invention as a whole" standard for claim analysis. The analysis in *In re Clement* states,

"If the reissue claims is as broad as or broader in an aspect germane to a prior art rejection, but narrower in another aspect completely unrelated to the rejection, the recapture rule bars the claim...."

Id., at 1165 (emphasis added). As so articulated by the Court, the relevance of the subject claim aspect is to the "prior art rejection," without regard to whether the specific aspect itself was at issue. Moreover, it is axiomatic that it is the entirety of a claimed invention which is the subject of any given rejection – not simply an individual claim element. Insofar as the below the melting point claim element is effective to distinguish the art cited in prosecution of the '626 Patent, it is manifestly relevant to the rejection, as it is part of the invention as a whole. Applicant submits that one cannot parse out individual elements as being "an issue" with respect to the rejection. Such is certainly not the rule articulated in *In re Clement*.

To the contrary, the "not at issue" analysis in the Answer underscores the materiality of the below the melting point limitation consistent with *Hester Industries v. Stein, Inc.*, 46 U.S.P.Q.2d 1641 (Fed. Cir. 1998). The Court in *Hester Industries* stated,

Finally, because the recapture rule may be avoided in some circumstances, we consider whether the reissue claims were materially narrowed in other respects. See, e.g. , *Mentor* , 998 F.2d at 996, 27 USPQ2d at 1525 ("Reissue claims that are broader in certain respects and narrower in others may avoid the effect of the recapture rule."); *Clement* , 131 F.3d at 1470, 45 USPQ2d at 1165. For example, in *Ball* the recapture rule was avoided because the reissue claims were sufficiently narrowed (described by the court as "fundamental narrowness") despite the broadened aspects of the claims. 729 F.2d at 1438, 221 USPQ at

296. In the context of a surrender by way of argument, this principle, in appropriate cases, may operate to overcome the recapture rule when the reissue claims are materially narrower in other overlooked aspects of the invention. The purpose of this exception to the recapture rule is to allow the patentee to obtain through reissue a scope of protection to which he is rightfully entitled for such overlooked aspects.

Id., 1649, 1650 (emphasis added). Applicants submit that the below the melting point limitation is just such an “overlooked aspect” of the invention. Indeed, as now argued by the Examiner, this limitation was “not an issue” during prosecution of the ‘626 Patent. That is, the limitation added to the appealed reissue claims was overlooked during prosecution of the ‘626 Patent.

The *Hester Industries* court provided no explicit guidance on what is meant by “overlooked.” The M.P.E.P. states, “A limitation that had been prosecuted in the original patent application is not directed to “overlooked aspects”” §1412.02(V), Manual of Patent Examining Procedure (8th ed 2001) (Rev 7, July 2008). Such is not the case with respect to the below the melting point limitation; the limitation was never presented (as recognized by the Examiner). Moreover, the present case can be distinguished from the facts of *Hester Industries*, where recapture was found because an added limitation was not “overlooked.” Specifically, the limitations added during prosecution of the reissue claims in *Hester Industries* were found to have been included in the claims as filed, and to have been argued to overcome a rejection. Such is not the case with respect to the below the melting point limitation of the appealed claims.

In sum, Applicants’ reissue claims, while having elements arguably broader than corresponding elements in the ‘626 Patent claims, embody limitations that materially narrow the claims in a way to obviate the recapture rejection. This materiality is evidenced not just technically, but by the relevance of the limitation to the prosecution of the ‘626 Patent (as per *In re Clements*) and as an overlooked aspect of the invention (as per *Hester Industries*). Thus, the reissue claims do not violate the recapture rule. Applicants respectfully request the rejection be reversed.

II. The claims are non-obvious in view of the combined *Zachariades* and *Kitamaru* references because the combination is made only through impermissible hindsight, as is evident from the Answer.

Claims 104, 109-111, 139, 149-153, and 164-168 are rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,030,402, *Zachariades* '402, issued July 9, 1991 in view of U.S. Patent No. 3,886,056, *Kitamaru*, issued May 27, 1975.

As discussed in the Brief, the present obviousness rejection attempts to reach the subject matter of the claims by (1) combining two references dealing with fundamentally different material technologies, (2) combining them in a fashion inconsistent with the process taught by the primary *Zachariades* '402 reference, and (3) arbitrarily selecting only certain features of the secondary *Kitamaru* reference for the combination. This combination represents an improper reconstruction of the references, guided only by impermissible hindsight use of Applicants' disclosure.

In particular, *Zachariades* '402 teaches heating thick polyethylene articles (such as prosthetic components) at a temperature below the melting point in order to compression deform, but does not teach irradiating before heating. *Kitamaru*, on the other hand, teaches to deform polyethylene fibers, films and sheets by extension above the melting point after irradiation. To reach the claims, one of the features of *Kitamaru* (irradiation before heating) must be combined with *Zachariades* '402, but another aspect (melting the polyethylene) must not be combined with *Zachariades* '402. Applicants submit this combination is only made with the benefit of hindsight reconstruction, notwithstanding the fact that the references deal with different material properties and the combination is inconsistent with the teachings of *Zachariades* '402.

Addressing Applicant's argument, the Answer (page 14) states (emphasis added):

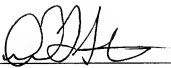
Appellant argues that only certain features of the secondary reference are arbitrarily selected, specifically "crosslinking before extending" from the disclosure of Kitamaru et al. This argument is not persuasive because, in the rejection of record, Kitamaru et al is relied upon for teaching that irradiated polyethylene can be compression-deformed and cooled.

This is the only modification of the teaching of Zachariades required to arrive at the instantly claimed method.

This analysis underscores the fact that disparate teachings of the prior art were pieced together using the claims as a guide or roadmap. It also overlooks the fact that one of ordinary skill would not combine references dealing with different material technologies or combine them in a fashion inconsistent with their teachings. Thus, it appears the only reason the *Kitamaru* feature of deforming above the melting point was not combined with *Zachariades* '402 was that such a combination would not have led to the subject matter of the rejected claims. Such an analysis is impermissible. See, *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 82 U.S.P.Q.2d 1385, 1397 (2007). ("A fact finder should be aware ... of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning") (internal citations omitted). *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546, 48 U.S.P.Q.2d 1321, 1329 (Fed. Cir. 1998) ("Determination of obviousness can not be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention."). See also *In re Fine*, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988) ("One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention."). A motivation to combine is still required, but "the motivation to combine references can not come from the invention itself." *Heidelberger Druckmaschinen AG v. Hantscho Commercial Products, Inc.*, 21 F.3d 1068, 1072, 30 U.S.P.Q.2d 1377, 1380 (Fed. Cir. 1993). At least because of this (as well as the other reasons discussed in the Brief), a proper *prima facie* case of obviousness is not supported, and the rejections under 35 USC 103(a) should be reversed.

Respectfully submitted,

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